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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,023	01/30/2006	Benny Pesach	34718	3188

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EXAMINER	
LIPITZ, JEFFREY BRIAN	
ART UNIT	PAPER NUMBER
4128	
MAIL DATE	DELIVERY MODE
03/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,023	PESACH ET AL.	
	Examiner	Art Unit	
	JEFFREY LIPITZ	4128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/30/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-10,13-17,20-23,25,26,29,30,34-36 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-10,13-17,20-23,25,26,29,30,34-36 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/27/2006, 12/6/2006,08/6/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 34 and 36 are objected to because of the following informalities: The phrase "in the neighborhood of" is unnecessary. If the drill is not within “drilling distance” of the region the hole cannot be formed. There is a true distance that is known or should be ascertained to define where the drill is positioned to form holes. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The relationship between wavelength of the light pulse and increasing the difference of the response to damaged or undamaged tissue is critical or essential to the practice of the invention, but not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 6, 8-10, 13-17, 20-23, 25, 26, 29, 30, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim et al (US 6,200,310), hereinafter Ben-Haim.

Regarding claim 1, Ben-Haim teaches a laser source (60) that is a means for removing tissue from a region to form a hole (Column 9, Lines 25-33), a light source (61) that illuminates the region with non-ablating light that generates photoacoustic waves (Column 7, Lines 15-20; Column 9, Lines 52-59), acoustic sensors (41,92) that generates signals responsive to the photoacoustic waves (Column 4, Lines 27-57; Column 9, Lines 52-59), and a controller (58) that receives the signals and processes them to determine a depth for the hole (Column 7, Lines 20-28; Column 8, Lines 9-34). Although Ben-Haim does not explicitly teach that the light generates photoacoustic waves or that the sensor generates signals responsive to photoacoustic waves, the reference does teach an ultrasound sensor, which obviously would detect photoacoustic waves generated by the light. In addition, photoacoustic waves are generated by absorption of energy from the light source, which leads to thermal expansion and emission of ultrasonic (acoustic) waves. Therefore, tissue and blood exposure to any light for a long enough time will lead to the generation of photoacoustic waves.

Regarding claim 2, Ben-Haim teaches the light source (61) obviously capable of illuminating the region with at least one pulse of light at a wavelength at which light is absorbed by a substance in the region whose concentration can be used to assess a degree of ischemia in the region and wherein the controller (58) processes the signals provided by the acoustic sensors (41,92) to assay the substance (Column 8, Lines 9-19;

Column 9, Lines 52-59). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In the instant case, the recitation of what illuminating the region should enable does not impose any additional structural limitations on the invention beyond that of the independent claim. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 6, Ben-Haim teaches the light source (61) capable of illuminating the region with at least one pulse of light at a wavelength at which light is absorbed by water and determines temperature of the region responsive to the signals (Column 7, Lines 15-20; Column 8, Lines 40-54).

Regarding claim 8, Ben-Haim teaches the light source (61) capable of illuminating the region with at least one light pulse prior to forming the hole and the controller (58) processes the signals to determine a thickness of the heart wall in the region (Column 8, Lines 9-34; Column 9, Lines 52-67). Ben-Haim does not explicitly teach that the signals will help to determine the thickness of the heart wall. However, a wavelength can be chosen that when light illuminates the interior of the heart, it will also pass through the heart muscle. When light passes through the interior and exterior surfaces of the muscle wall part of the light will be reflected, part refracted, and part absorbed. The portion of light that is absorbed can generate photoacoustic waves that will be detected by the sensor. The time delay between the generations of the two sets of waves is proportional to the distance between the two surfaces (the thickness of the heart wall). Ben-Haim does teach that the signals processed from the controller are

used to map the channel location and dimensions prior to drilling (Column 8, Lines 20-26). In order to determine the optimal dimensions and orientations of the holes, it is necessary to know the thickness of the heart wall, since drilling a hole too deep could compromise the integrity of the heart. The claimed recitation of the intended use of the claimed invention (illuminating the region with a light pulse) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claims 9, 10, and 13, Ben-Haim teaches the controller (58) capable of controlling the means for removing tissue (60) from the region responsive to the determined depth of the hole and thickness of the heart muscle, and stops formation of the hole by the means for removing tissue when a desired hole depth is reached. Acoustic sensors (41,92) receive signals that are processed by the controller (58) that can be used to ascertain the thickness of the heart wall, as described in the rejection of claim 8 (Column 7, Lines 20-33; Column 8, Lines 8-34; Column 9, Lines 52-59). A recitation of the intended use of the claimed invention (the actions of the controller) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claims 14 and 15, Ben-Haim teaches the source of ablative energy having an output port (54) from which the ablative energy source provides energy for removing heart tissue (Column 7, Lines 3-19). The distance between the ablative

energy output port and the bottom of the hole must be able to be determined for the controller (58) to map out the location and depth of the channel (Column 8, Lines 30-40). The theory behind sensing acoustic waves, generated by tissue, to form images rests on the fact that sound travels at a constant speed. Therefore, if it is known how much energy is required to generate acoustic waves in a tissue, the energy emission is kept constant and the catheter is not moved (there is a constant distance), there will be a time delay between emission of the light and the sensing of the acoustic waves generated therefrom. Using the known speeds of light and sound, the distance between the output of the light and the tissue could obviously be determined.

Regarding claim 30, there are substantially similar limitations to those of 9, 10, and 13-15, please see the rejections of those claims discussed supra.

Regarding claims 16, 17, 20, 21, 22, 23, 25, 26, 29 and 35, Ben-Haim teaches a controller (58) capable of controlling at least one characteristic of the least one ablative pulse responsive to the signal generated by the acoustic sensor (Column 7, Lines 20-28; Column 8, Lines 28-34). Examiner interprets the waves detected by the acoustic sensor to be shock waves or reflections of acoustic energy from the shock wave. The controller can process the signals to determine at least one characteristic of the shock wave (Column 8, Lines 28-34). Examiner notes that any signal detected by the sensor is a characteristic of the wave, such as amplitude, frequency or phase. The information relayed to the sensor is used to *indirectly* determine structural features or other properties of the tissue or the source of the waves (Column 9, Lines 52-59, Column 8, Lines 20-27). Examiner notes that “mapping” the designated location of the channel

requires acquiring, from the sensors, the location of the diseased tissue. The characteristics can be depth and location of the hole, the thickness of the heart muscle between the bottom of the hole and a surface of the wall, and damage tissue (Column 7, Lines 20-33; Column 8, Lines 8-34; Column 9, Lines 52-59). Examiner interprets low tissue oxygenation as an indication of tissue damage (Column 9, Lines 52-58). Obviously, the point of the controller receiving signals about the shock wave, is to adjust the laser treatment (the "at least one ablative pulse") accordingly. Although Ben-Haim does NOT teach using the acoustic sensors to determine the wavelength of the light pulses so as to increase a difference in the photoacoustic response between damaged and undamaged tissue, when such a sensor is used the wavelength of the pulses are obviously optimized to elicit a regular and predictable photoacoustic response. Otherwise, the technique could not be reliably used. The same wavelength of light will be absorbed or reflected differently by damaged and undamaged tissue. Using a wavelength that is almost entirely absorbed by one type of tissue will reduce reflection from that type of tissue, increasing the signal generated by the other tissue type. Varying the wavelength to increase the photoacoustic response of one tissue relative to another is not of innovation, but an obvious and neccessary optimization of the system to reduce noise.

Regarding claims 34 and 36, wherein there is a catheter (52,53) having a drill end (64) that is positioned above the region or in contact with the region in order to form the hole and wherein the optical output aperture (62), the ablative energy output port

(54), and an acoustic sensor (41) are mounted inside the catheter (52,53) near the drill end (Figure 4).

6. Claims 7 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Haim, in view of Spears et al. (US 5,019,075), hereinafter Spears.

Regarding claim 7, Ben-Haim teaches a controller (58) obviously capable of processing signals from the sensors on the catheter, and an acoustic sensor. Although Ben-Haim does not teach using the acoustic sensor for determining temperature changes over time, applicant provides two prior art citations that show how to determine temperature changes over time with an acoustic sensor (Applicant's Disclosure: Page 14, Lines 23-29). Ben-Haim DIFFERS in that he does not disclose a heat pump that generates a temperature difference between tissue in the region and an ambient temperature of the heart wall, as claimed. Attention, however, is directed to Spears which, in the same area of endeavor, discloses another apparatus for treatment of ischemic heart disease that contains a heat pump comprised of a diffusing tip (32), a balloon (34) and laser radiation for generating a temperature difference between tissue in the region and an ambient temperature of the heart wall (Column 8, Lines 42-59). Examiner interprets a heat pump as any apparatus capable of generating a temperature difference between tissue in the region and the ambient temperature of the heart wall. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Ben-Haim to incorporate the teachings of Spears, in order to allow for another diagnostic measure of cardiac function.

Regarding claim 39, Ben-Haim also DIFFERS in that it does not disclose an external acoustic sensor as claimed. Attention, however, is also directed to Spears, which discloses another apparatus for treatment of ischemic heart disease that contains an acoustic sensor that is placed external to the body (Column 5, Lines 21-37). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the teachings of Spears with those of Ben-Haim, because doing so would enable choosing an ideal location to place the sensor in order to maximize the acoustic signal and minimize noise.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Friday from 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Khoa Huynh can be reached on 571-272-4888. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY LIPITZ/
Examiner, Art Unit 4128

/Khoa D. Huynh/
Supervisory Patent Examiner, Art Unit 4128